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S E C T O R S
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P A T E N T & T R A D E M A R K C E N T E R

Application Number	09/830,045
Filing Date	April 20, 2001
First Named Inventor	Rose-Mary N. Boustany
Group Art Unit	Unknown 1634
Examiner Name	Unknown Goldberg
Attorney Docket Number	5405.225

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code (if known)			
gn	1	4,599,308		Hamer et al.	7/8/86	
	2	4,797,368		Carter et al.	1/10/89	
	3	5,139,941		Muzyczka et al.	8/18/92	
	4	5,173,414		Lebkowski et al.	12/22/92	
	5	5,176,996		Hogan et al.	1/5/93	
	6	5,252,479		Srivastava	10/12/93	
	7	5,288,514		Ellman	2/22/94	
	8	5,354,678		Lebkowski et al.	10/11/94	
	9	5,436,146		Shenk et al.	7/25/95	
	10	5,445,934		Fodor et al.	8/29/95	
	11	5,468,634		Liu	11/21/95	
	12	5,474,935		Chatterjee et al.	12/12/95	
	13	5,518,913		Massie et al.	5/21/96	
	14	5,565,324		Still et al.	10/15/96	
	15	5,585,269		Earp, III et al.	12/17/96	
	16	5,585,362		Wilson et al.	12/17/96	
	17	5,587,308		Carter et al.	12/24/96	
	18	5,589,477		Chokai et al.	12/31/96	
	19	5,604,090		Alexander et al.	2/18/97	
	20	5,616,326		Spibey	4/1/97	
	21	5,622,856		Natsoulis	4/22/97	
	22	5,650,318		Aggarwal et al.	7/22/97	
	23	5,658,776		Flotte et al.	8/19/97	
	24	5,670,488		Gregory et al.	9/23/97	
	25	5,677,158		Zhou et al.	10/14/97	
	26	5,681,731		Lebkowski et al.	10/28/97	
	27	5,707,865		Kohn et al.	1/13/98	
	28	5,734,039		Calabretta et al.	3/31/98	
	29	5,747,335		Haseloff et al.	5/5/98	
	30	5,766,942		Haseloff et al.	6/16/98	
	31	5,773,260		Goldberg et al.	6/30/98	
	32	5,811,537		Griesen	9/22/98	
	33	5,817,635		Eckstein et al.	10/6/98	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T
gn	34	Altschul, et al., <i>Basic Local Alignment Search Tool</i> , <i>J. Mol. Biol.</i> , Vol. 215, pp. 403-410 (1990)	
gn	35	Amarnath, et al., <i>Chemical Synthesis of Oligonucleotides</i> , <i>Chemical Reviews</i> , Vol. 77, No. 2, pp. 193-217 (1977)	
	36	Andersson, et al., <i>Cloning, Structure, and Expression of the Mitochondrial Cytochrome P-450 Sterol 26-Hydroxylase, a Bile Acid Biosynthetic Enzyme</i> , <i>Journal of Biological Chemistry</i> , Vol. 264, No. 14, pp. 8222-8229 (1989)	
	37	Arends, et al., <i>Apoptosis: The Role of the Endonuclease</i> , <i>American Journal of Pathology</i> , Vol. 136, No. 3, pp. 593-608)	

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OTHER PRIOR ART / NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T
gj	38	Atherton, et al., <i>The Solid Phase in Solid-Phase Synthesis, Perspectives in Peptide Chemistry</i> , pp. 101-117 (Karger, Basel 1981)	
	39	Bligh, et al., <i>A Rapid Method of Total Lipid Extraction and Purification, Canadian Journal of Biochemistry and Physiology</i> , Vol. 37, No. 8, pp. 911-917 (August 1959)	
	40	Boustany, et al., <i>Neurological Progress – The Neuronal Ceroid Lipofuscinoses: A Review, Revue Neurologique</i> , Vol. 145, No. 2, pp. 105-110 (1989)	
	41	Boustany, Rose-Mary, <i>Neurology of the Neuronal Ceroid-Lipofuscinoses: Late Infantile and Juvenile Types, American Journal of Medical Genetics</i> , Vol. 42, pp. 533-535 (1992)	
	42	Boustany, et al., <i>Clinical Classification of Neuronal Ceroid-Lipofuscinosis Subtypes, American Journal of Medical Genetics Supplement</i> , Vol. 5, pp. 47-58 (1988)	
	43	Fieck, et al., <i>Modifications of the E. coli Lac repressor for expression in eukaryotic cells: effects of nuclear signal sequences on protein activity and nuclear accumulation, Nucleic Acids Research</i> , Vol. 20, No. 7, pp. 1785-1791 (April 11, 1992)	
	44	Friedmann, Theodore, <i>Progress Toward Human Gene Therapy, Science</i> , Vol. 244, pp. 1275-1281 (June 16, 1989)	
	45	Fridkin, Mati, <i>Polymeric Reagents in Peptide Synthesis, The Peptides</i> , Vol. 2, pp. 333-363 (1979)	
	46	Stoll, et al., <i>Effect of Vincristine on Sister Chromatid Exchanges of Normal Human Lymphocytes, Cancer Research</i> , Vol. 36, pp. 2710-2713 (August 1976)	
	47	Howard, et al., <i>Cell Cycle Arrest of Proliferating Neuronal Cells by Serum Deprivation Can Result in Either Apoptosis or Differentiation, Journal of Neurochemistry</i> , Vol. 60, No. 5, pp. 1783-1791 (May 1993)	
	48	Kaufmann, et al., <i>Specific Proteolytic Cleavage of Poly(ADP-ribose) Polymerase: An Early Marker of Chemotherapy-induced Apoptosis, Cancer Research</i> , pp. 3976-3985 (September 1, 1993)	
	49	Obeid, et al., <i>Programmed Cell Death Induced by Ceramide, Science</i> , Vol. 259, pp. 1769-1771 (March 19, 1993)	
	50	Perry, et al., <i>Bcl-2 acts upstream of the PARP protease and prevents its activation, Cell Death and Differentiation</i> , Vol. 4, No. 1, pp. 29-33 (1997)	
	51	Rosenbaum, et al., <i>Evidence of Hypoxia-induced, Programmed Cell Death of Cultured Neurons, Annals of Neurology</i> , Vol. 36, No. 6, pp. 864-870	
	52	Walker, P. Roy, et al., <i>Topoisomerase II-reactive Chemotherapeutic Drugs Induce Apoptosis in Thymocytes, Cancer Research</i> , Vol. 51, No. 4, pp. 1078-1085 (February 15, 1991)	
	53	Woo, Savio L.C., <i>Adenovirus redirected, Nature Biotechnology</i> , Vol. 14, No. 11, pp. 1538 (November 1996)	
	54	Lee, et al., <i>Ceramide Inactivates Cellular Protein Kinase Cα*, Journal of Biological Chemistry</i> , Vol. 271, No. 22, pp. 13169-13174 (May 31, 1996)	
	55	Zhang, et al., <i>Bcl-2 interrupts the ceramide-mediated pathway of cell death, Proc. Natl. Acad. Sci. USA</i> , Vol. 93, pp. 5325-5328 (May 1996)	
	56	Bertrand, et al., <i>Induction of a Common Pathway of Apoptosis by Staurosporine, Experimental Cell Research</i> , Vol. 211, pp. 314-321 (1994)	
	57	Boustany, R-M, et al., <i>Seizures, Depression and Dementia in Teenagers with Batten Disease, J. Inher. Metab. Dis.</i> , Vol. 16, pp. 252-255 (1993)	
	58	Griffith, et al., <i>Fas Ligand-Induced Apoptosis as a Mechanism of Immune Privilege, Science</i> , Vol. 270, pp. 1189-1193 (November 17, 1995)	
	59	Griffith, et al., <i>CD95-Induced Apoptosis of Lymphocytes in an Immune Privileged Site Induces Immunological Tolerance, Immunity</i> , Vol. 5, pp. 7-16 (July 1996)	
	60	Hannun, Yusuf A., <i>Functions of Ceramide in Coordinating Cellular Responses to Stress, Science</i> , Vol. 274, pp. 1855-1859 (December 13, 1996)	
	61	Janes, et al., <i>A model of Batten disease protein CLN3: Functional implications from homology and mutations, Federation of European Biochemical Societies</i> , Vol. 399, pp. 75-77 (1996)	
	62	Kulkarni, et al., <i>Serum deprivation induces apoptotic cell death in a subset of Balb/c 3T3 fibroblasts, Journal of Cell Science</i> , Vol. 107, pp. 1169-1179 (1994)	
	63	Lane, et al., <i>Apoptosis as the Mechanism of Neurodegeneration in Batten's Disease, Journal of Neurochemistry</i> , Vol. 67, No. 2, pp. 677-683 (1996)	
	64	Liu, et al., <i>Induction of Apoptotic Program in Cell-Free Extracts: Requirement for dATP and Cytochrome c, Cell</i> , Vol. 86, pp. 147-157 (July 12, 1996)	
	65	Mitchison, et al., <i>Genomic Structure and Complete Nucleotide Sequence of the Batten Disease Gene, CLN3, Genomics</i> , Vol. 40, pp. 346-350 (1997)	
	66	Peña, et al., <i>Stress-Induced Apoptosis and the Sphingomyelin Pathway, Biochemical Pharmacology</i> , Vol. 53, pp. 615-621 (1997)	

Examiner Signature

G. Goldberg

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SG	67	Puranam, et al., <i>Upregulation of Bcl-2 and Elevation of Ceramide in Batten Disease</i> , <i>Neuropediatrics</i> , Vol. 28, pp. 37-41 (1997)	
	68	Smyth, et al., <i>priCE: a downstream target for ceramide-induced apoptosis and for the inhibitory action of Bcl-2</i> , <i>Biochem. J.</i> , Vol. 316, pp. 25-28 (1996)	
	69	The International Batten Disease Consortium, <i>Isolation of a Novel Gene Underlying Batten Disease</i> , <i>CLN3, Cell</i> , Vol. 82, pp. 949-957 (September 22, 1995)	
	70	White, Eileen, <i>Life, death, and the pursuit of apoptosis</i> , <i>Genes & Development</i> , Vol. 10, pp. 1-15 (1996)	

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S. Goldberg

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